REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

Applicants wish to thank the Examiner for taking the time to discuss this case during the telephonic interview dated 15 September 2006 ("Interview").

This Amendment is filed concurrently with a Petition for a **One (1) Month** Extension of Time, which extends the time of response from 5 September 2006 to 5 October 2006, and a Request for Continued Examination ("RCE") in lieu of filing an Appeal Brief in response to the Notice.

Claims 8 and 14 were amended to highlight that the "effective amount" is "from about 1 to about 15 mg." Support for this language may be found in the Specification as originally filed at, for example, page 2, line 30 to page 3, line 4, and as such does not introduce new matter into the application.

Claims 1 – 7, 9 – 13, and 16 – 17 were cancelled without prejudice to the refiling of these claims in a subsequent continuation application. After entry of this amendment, claims 8, 14, and 15 are pending, of which claims 8 and 14 are independent.

In the Office Action, claims 1, 3, 5, 8, 14 and 15 were rejected under Section 103(a) as obvious over Stevens (US 5,599,577), in view of Drug Launches (1993), Schmidt et al. (US 5,424,064) ("Schmidt ('064)"), Holtmann et al. ("Holtmann") and Gaginella et al., "Nitric Oxide as a Mediator of Disacodyl and Phenolphthalein Laxative action: Induction of Nitric Oxide Synthase," 270(3) Jl. Pharmacol. And Exp. Ther.," 1239 (1994)("Gaginella").

Applicants further wish to point out that claims 1, 3, 5, 8, 14 and 15 were allowed previously over Drug Launches (1993), Schmidt et al. (US 5,424,064) ("Schmidt ('064)"), and Holtmann et al. ("Holtmann") as set forth in the Notice of Allowability dated 11 June 2005 ("Notice").

The Rejection of Claims 1, 3, 5, 8, 14 and 15 under 35 U.S.C. §103(a) Over Stevens, in view of Drug Launches, Schmidt (064), Holtmann, and Gaginella Has Been Overcome

Claims 1, 3, 5, 8, 14 and 15 stand rejected under Section 103(a) as obvious over Stevens, in view of Drug Launches, Schmidt ('064), Holtmann, and Gaginella. Applicants respectfully disagree for the reasons that follow.

In view of the cancellation of claims 1, 3, and 5, Applicants respectfully submit that the rejection of these claims has been overcome and should be withdrawn.

As set forth in the Notice, all of these claims were found to contain allowable subject matter over Drug Launches, Schmidt ('064), and Holtmann. Therefore, the only art that is newly cited in the Office Action but not in the Notice is Stevens and Gaginella. Applicants maintain that these two references fail to disclose or suggest any additional subject matter that would render the present claims as unpatentable.

A. **Stevens**

According to the Office Action, Stevens "disclose[s] the combination of simethicone... to a patient suffering from gas and a pharmaceutical suitable for treatment of gastrointestinal disorders." Stevens then particularly discloses pharmaceutical agents suitable for, for example, treating diarrhea. See Stevens, column 4, lines 51 - 67. However, Stevens fails to disclose or suggest, for example:

1) the use of laxation agents or "small bowel motility agents," either alone or in combination with simethicone;
2) the particular combination of simethicone and bisacodyl for the claimed methods;
3) the use of bisacodyl to " improve[e] small bowel motility;" or
4) the use of simethicone to "enhance[e] the small bowel motility increasing effect of bisacodyl"

as presently claimed.

B. **Gaginella**

With respect to Gaginella, Applicants wish to correct an inadvertent error made in Applicant's previous Response, which provided that "Gaginella taught the use of 25 mg/kg of bisacodyl." Rather, as disclosed on page 1240, 4th full paragraph, of Gaginella, Gaginella taught the use of 50 mg/kg of bisacodyl, which is significantly higher than the amount claimed herein.

Applicants respectfully submits that Gaginella neither discloses nor suggests, for example,:

1) the use of the combination of bisacodyl with simethicone;

2) the use of an amount of bisacodyl that is significantly less than 50 mg/kg;

3) the use of the combination of bisacodyl with simethicone in a "method of improving small bowel motility;"

4) the use of simethicone in a "method for enhancing the small bowel motility increasing effect of bisacodyl"

5) the use of an amount of bisacodyl that is significantly less than 50 mg/kg in a "method of improving small bowel motility;" or

6) the use of "from about 1 mg to about 15 mg of bisacodyl"

as claimed herein.

Moreover, as discussed during the Interview and as shown in Example 1, page 6 of the Specification, Applicants have unexpectedly found that the use of the claimed combination of simethicone with bisacodyl is significantly more effective in increasing small bowel transit relative to the use of bisacodyl alone or simethicone alone.

For these reasons, Applicants again submit that the claims are patentable. Early and favorable reconsideration is requested.

Respectfully submitted,

McNally, et al.

By: /Michele G. Mangini/
Michele G. Mangini
Reg. No. 36,806
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2810
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Att.
Petition for a One (1) Month Extension of Time,
RCE